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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/359,300	07/21/1999	MONTO H. KUMAGAI	08010137US07	2643

25871 7590 07/02/2003

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

42

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/359,300

Applicant(s)

KUMAGAI ET AL.

Examiner

Gerald G Leffers Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45 and 60-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45 and 60-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 1/14/03 as Paper No. 39, in which claims were amended (claims 45, 62 & 63). Receipt is also acknowledged of a supplemental response in which a corrected marked-up copy of the claims submitted in Paper No. 39 was filed in response to a Notice of Nonresponsive Amendment mailed 3/26/03 (Paper No. 40). This supplemental response was filed as Paper No. 41 on 4/21/03. Claims 45, 60-70 are pending in the instant application.

Any rejection of record in the previous office actions that is not addressed herein is withdrawn. This action is not final as new grounds of rejection are made herein that were not necessitated by applicants' amendment of the claims in Paper No. 39.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45, 60-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

Each of the claims is directed towards a method of determining the presence of a trait in a plant wherein an unidentified nucleic acid is obtained from a cDNA or gDNA library of a non-plant donor, and wherein the unidentified nucleic acid is comprised within a "recombinant plant

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viral nucleic acid". The viral nucleic acid is transfected into a target plant host cell and the unknown nucleic acid expressed in the target host cell. Claim 45 specifies that the viral nucleic acid is a plant viral nucleic acid. The term "viral nucleic acid" is not clearly defined in the specification in the context of the claimed methods and can encompass embodiments having only a very limited identity with a plant virus (see the 112 2nd rejection below). A reasonably broad interpretation of the phrase "plant viral nucleic acid" is that it encompasses any nucleic acid that comprises at least one nucleotide present in a plant virus. The claim further stipulates that the unidentified nucleic acid is "transiently" expressed in the target host plant. The specification essentially defines "transient" expression as any expression in a plant host from a vector wherein the expression is not permanent (e.g. in transgenic plants, or from a vector incorporated into the host genome; see for example page 6, line 5 or page 27, lines 7-14). Thus, the claims embrace an enormously broad genus of possible nucleic acid sequences derived from a viral source which must also meet the functional limitation of directing "transient" expression of the unidentified nucleic acid insert.

The specification has described a series of plant and animal vectors which might serve as viral vector for expression of nucleic acids in a plant host. No significant description is provided, however, for non-viral vectors capable of transient expression of heterologous nucleic acids in target plant host. In fact, the only vectors that are described in the instant specification as suitable for meeting the functional limitation of the claims (i.e. "transient" expression) are plant vectors obtained from a plant RNA virus (e.g. tobacco mosaic virus (TMV), cowpea mosaic virus (CMV), etc.; see pages 14-15, bridging paragraph). The instant specification teaches that transient expression of heterologous nucleic acids is possible due to the presence of

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a subgenomic promoter that allows for the systemic expression of a positive sense RNA comprising the heterologous sequence. There is no basis provided in the specification, however, for one of skill in the art to be able to envision other embodiments of the claimed invention wherein the "recombinant plant viral nucleic acid" is not a recombinant plant viral vector obtained from a plant RNA virus. Nor does the prior art appear to offset the deficiencies of the instant specification with regard to any type of vectors other than RNA viral vectors that are capable of the type of transient transfection required in the rejected claims. Thus, there is no basis for the skilled artisan to envision a representative number of embodiments of "recombinant plant viral nucleic acids" embraced by the rejected claims and which satisfy the functional limitations of the claims. Therefore, one of skill in the art would reasonably conclude applicants' were not in possession of the claimed invention. It would be remedial to amend the claim language to recite that the unidentified nucleic acid inserts are cloned into a plant RNA viral vector prior to their transient expression in the infected plant host.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45, 60-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection.**

Claim 45 is vague and indefinite in that the metes and bounds of the phrase "plant viral nucleic acids" are unclear. It is unclear as the phrase is written whether the phrase encompasses literally any nucleic acid sequence that comprises a sequence present in a plant virus or whether

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the phrase is intended to specify a vector obtained from a plant virus. Upon reading the instant specification and in view of the rest of the claim language, it appears that the phrase is intended to specify a plant viral vector. It would be remedial to amend the claim language to recite that the unidentified nucleic acid inserts are inserted into a plant viral vector.

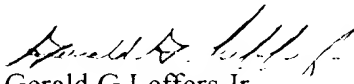
Conclusion

No claims are allowed. The claims appear to be free of the art

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl
June 27, 2003